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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,212	01/04/2002	John Colyer	10069/1004	6487

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,212	COLYER ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-91* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Part III DETAILED ACTION

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to polypeptides, classified in class 530, in general.

I.1 Claims 1-18 in part drawn to polypeptides carrying an engineered site sufficient for the addition of phosphate moiety, classified in class 530, in general.

I.2 Claims 1-18 in part drawn to polypeptides carrying an engineered site sufficient for the addition of ubiquitin moiety, classified in class 530, in general.

I.3 Claims 1-18 in part drawn to polypeptides carrying an engineered site sufficient for the addition of glycosyl moiety, classified in class 530, in general.

I.4 Claims 1-18 in part drawn to polypeptides carrying an engineered site sufficient for the addition of ADP-ribosyl moiety, classified in class 530, in general.

II. Claims 19-37, drawn to a kit comprising polypeptide, classified in class 435, subclass 810+.

II.1 Claims 19-37 in part drawn to kit comprising polypeptides carrying an engineered site sufficient for the addition of phosphate moiety, classified in class 435, subclass 810+.

II.2 Claims 19-37 in part drawn to kit comprising polypeptides carrying an engineered site sufficient for the addition of ubiquitin moiety, classified in class 435, subclass 810+.

II.3 Claims 19-37 in part drawn to kit comprising polypeptides carrying an engineered site sufficient for the addition of glycosyl moiety, classified in class 435, subclass 810+.

II.4 Claims 19-37 in part drawn to kit comprising polypeptides carrying an engineered site sufficient for the addition of ADP-ribosyl moiety, classified in class 435, subclass 810+.

III. Claims 38-52,91 drawn to method to monitor activity of an enzyme, classified in class 514, in general.

III.1 Claims 38-52,91 in part drawn to method to monitor activity of an enzyme comprising addition of phosphate moiety, classified in class 514, in general.

III.2 Claims 38-52,91 in part drawn to method to monitor activity of an enzyme comprising addition of ubiquitin moiety, classified in class 514, in general.

III.3 Claims 38-52,91 in part drawn to method to monitor activity of an enzyme comprising addition of glycosyl moiety, classified in class 514, in general.

III.4 Claims 38-52,91 in part drawn to method to monitor activity of an enzyme comprising addition of ADP-ribosyl moiety, classified in class 514, in general.

IV. Claims 53-57, drawn to a kit comprising fluorescently-labeled polypeptides, classified class 435, subclass 810+.

IV.1 Claims 53-57 in part drawn to polypeptides carrying an engineered site sufficient for the addition of phosphate moiety, classified in class 435, in general.

IV.2 Claims 53-57 in part drawn to polypeptides carrying an engineered site sufficient for the addition of ubiquitin moiety, classified in class 435, in general.

IV.3 Claims 53-57 in part drawn to polypeptides carrying an engineered site sufficient for the addition of glycosyl moiety, classified in class 435, in general.

IV.4 Claims 53-57 in part drawn to polypeptides carrying an engineered site sufficient for the addition of ADP-ribosyl moiety, classified in class 435, in general

V. Claims 58-66, drawn to a polypeptide dimer, classified in class 530, in general.

V.1 Claims 58-66 in part drawn to polypeptides carrying an engineered site sufficient for the addition of phosphate moiety, classified in class 530, in general.

V.2 Claims 58-66 in part drawn to polypeptides carrying an engineered site sufficient for the addition of ubiquitin moiety, classified in class 530, in general.

V.3 Claims 58-66 in part drawn to polypeptides carrying an engineered site sufficient for the addition of glycosyl moiety, classified in class 530, in general.

V.4 Claims 58-66 in part drawn to polypeptides carrying an engineered site sufficient for the addition of ADP-ribosyl moiety, classified in class 530, in general

VI. Claims 67-77, 91, drawn to method of screening for a modulator of enzyme activity using a polypeptide of Group I, which method depends upon the presence of a moiety, classified in class 514, in general.

VI.1 Claims 67-77, 91 in part drawn to the method employing phosphate moiety, classified in class 514, in general.

VI.2 Claims 67-77, 91 in part drawn to method employing ubiquitin moiety, classified in class 514, in general.

VI.3 Claims 67-77, 91 in part drawn to method employing glycosyl moiety, classified in class 514, in general.

VI.4 Claims 67-77, 91 in part drawn to method employing ADP-ribosyl moiety, classified in class 514, in general

VII. Claims 67-77, 91, drawn to method of screening for a modulator of enzyme activity using a polypeptide of Group I, which method depends upon the presence of a moiety, classified in class 514, in general.

VII.1 Claims 78-88,81 in part drawn to the method employing phosphate moiety, classified in class 514, in general.

VII.2 Claims 78-88,81 in part drawn to method employing ubiquitin moiety, classified in class 514, in general.

VII.3 Claims 78-88,81 in part drawn to method employing glycosyl moiety, classified in class 514, in general.

VII.4 Claims 78-88,81 in part drawn to method employing ADP-ribosyl moiety, classified in class 514, in general

VIII. Claims 89-90, 91 drawn to method to monitor activity of enzyme using a polypeptide covalently bound to a moiety, classified in class 514, in general.

VIII.1 Claims 89-90, 91 in part drawn to method using a polypeptide covalently bound to phosphate moiety, classified in class 514, in general.

VIII.2 Claims 89-90, 91 in part drawn to method using a polypeptide covalently bound to ubiquitin moiety, classified in class 514, in general.

VIII.3 Claims 89-90, 91 in part drawn to method using a polypeptide covalently bound to glycosyl moiety, classified in class 514, in general.

VIII.4 Claims 89-90, 91 in part drawn to method using a polypeptide covalently bound to ADP-ribosyl moiety, classified in class 514, in general

The term "distinct" means that two or more subjects as disclosed are related but are capable of separate manufacture, use, or sale as claimed, and are patentable (novel and unobvious) over each other (though they may each be unpatentable because of the prior art). (MPEP 802.01). The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and V are patentably distinct from each other because of the materially different structures of the compounds they are claiming.

The inventions I and II are distinct because the product of Group I is capable of a separate use, e.g., for peptide synthesis or production of antibodies.

The inventions I or V and invention IV are independent because the kit of the Group IV does not contain a product of Group I or V. Further, the products are capable of a separate use, e.g., for peptide synthesis or production of antibodies.

The product of Group I and methods of use of Groups III, VI, or the product of Group V and method of use of Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different processes such as peptide synthesis or production of antibodies. Further, the methods of use can be practiced with a broad variety of probes beyond the claimed peptide derivatives, for example, with spin-labeled probes.

The method of Group VIII is independent from the products of Groups I or V, because it does not utilize either of these products. Instead, the method utilizes a polypeptide covalently bound to a moiety.

The methods of Groups III, VI, VII, VIII are related as independent methods which are not connected in design, operation or effect. These methods are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the methods either have a different effect (e.g., monitoring activity of enzyme in methods of Groups III, VIII *vs* screening for modulators in methods of Groups VI, VII), or they have different method steps (e.g., monitoring addition of a moiety to a reporter, in method of Group III *vs* monitoring association of a peptide to a binding partner in method of Group VIII), or they utilize different products (e.g., method of group VI uses polypeptides with a site sufficient for addition of a moiety, whereas method of Group VIII uses a polypeptide covalently bound to a moiety, or method of Group VII uses paired bound peptides), or they are not disclosed as capable of being used together.

Group I consists of four separate, patentably distinct, groups which are not connected in a way required to maintain unity of invention. Unity of invention exists where compounds included within a Markush group share a common utility and share a substantial structural feature disclosed as being essential to that utility. In the instant case the product as claimed in claim 1 does not have any identifiable common core structure: the polypeptide part have no common core except for the engineered site which is differs depending on the target moiety and, again, has no common core

structure necessary tho hold the unity of invention. Accordingly, Group I is further divided into groups I.1-I.4 drawn to polypeptides carrying sites sufficient for addition to phosphate, ubiquitin, glycosyl and ADP-ribosyl moieties, respectively.

Groups II, IV, V, each, consists of four separate groups II.1-II.4, IV.1-IV.4, V.1-V.4, respectively, which are patentably distinct for the reasons set forth for Groups I.1-I.4, above.

Groups III, VI,VII, VIII each, consists of four separate groups III.1-III.4, VI.1-VI.4, VII.1-VII.4, VIII.1-VIII.4, respectively, drawn to independent methods. The methods are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the methods they utilize different products (e.g., peptides with a site sufficient for addition of a phosphate moiety *vs* a peptide with a site sufficient for addition of a ubiquitin moiety), and they are not disclosed as capable of being used together (i.e., a method utilizing on type of moiety is not capable of being used with another type of moiety).

Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If applicant elects claims directed to a product, and the product claims are subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (MPEP 821.04)

It is noted that claims 16-18, 34-36, are in improper dependent form as the failing to further limit the subject matter of a previous claim. The claims are drawn to polypeptides containing two coiled coils, whereas their base claims (e.g., 1, 14) are drawn to peptides comprising one coiled coil (see "a coiled coil" in claim 1). Applicant is required to cancel the claims, or rewrite the claims in independent form. In the latter case, the claims will, possibly, be a subject of a further restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Upon election of any single one of the Groups from above the following election of species is hereby required:

Species Requirement

The claims of Group are individually or dependently directed to a plurality of disclosed patentably distinct species of fluorescently labeled peptides. For the purposes of initial search for the examination on the merits applicant is required to elect a single disclosed species of one of the combinations of fluorescent labels, e.g., as in claims 9, 12, 13. Note, that a choice of subgenus species such as "fluorescent proteins" is not responsive. Please make an election of species from those listed as species in the claims.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds

one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

February 18, 2004

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb